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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER
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FORD, JOHN M

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 10/08/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/088916

Applicant(s)

Shinoda

Examiner

J. M. Ford

Group Art Unit

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—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE THREE MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

- ☐ Responsive to communication(s) filed on \_\_\_\_\_.
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- ☒ Claim(s) 1-18 is/are pending in the application.
- Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☐ Claim(s) 1-18 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☒ Claim(s) 1-18 are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
  - ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.
  - ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.
  - ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

\*Certified copies not received: \_\_\_\_\_

## Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_ ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892 ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948 ☐ Other \_\_\_\_\_

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The claims in the application are claims 1—18.

In claim 1, page 442. What is the purpose of the proviso statement at the end of claim? If the “above definition is excluded” page 442, line 4, what is it?

Claim 1 is rejected under 35 U.S.C. 112, 2<sup>nd</sup> paragraph, at the end of claim 1, what are the hetero atoms? Similarly, “one or more” could not be allowed.

Claim 6 is rejected under 35 U.S.C. 112, 2<sup>nd</sup> paragraph. Last line “which have one or more substitu<sup>ents</sup>” is not limited from infinity, and does not say what the substitutions are. Same, claim 9 and 10,

Claims 11—16 are rejected as non-statutory. A medicament is not a proper method claim or a proper composition claim.

Any claim not specifically rejected, is rejected as being dependent on a rejected claim.

Claim 17 is rejected under 35 U.S.C. 112, 1<sup>st</sup> paragraph. A method of preventing a specific disease is required. Treating diseases against which PPAR  $\alpha$ ,  $\beta$ ,  $\gamma$  dual agonist or, PPAR  $\alpha$ ,  $\beta$ ,  $\gamma$  triple agonism <sup>is</sup> efficacious, *is not a real world utility.*  
Triple agonism is efficacious is not one utility. See pages 3 and 4 of the specification.

The recent utility guidelines set by PTO require applicants to meet the requirements as stated in Brenner v. Manson in, 148 USPQ 689, which requires that utility be developed to a point where “specific benefits in currently available form”. Similar is the “immediate benefit to the public” standard that Nelson v. Bowler, 206 USPQ 880 refers to. The standard set forth in the concurring

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opinion of *In re Hartop*, 135 USPQ 419 is "whether the invention has been brought to such perfection as to be capable of practice employment". This language is echoed in *Bindra vs. Kelly*, 206 USPQ 570.

MPEP 806.05(h) provides for restriction. A broad disclosure of utility as in the cited claims cannot be deemed in compliance with 35 U.S.C. 101 and 35 U.S.C. 112, first paragraph. A real world utility required. The PTO has amended the guidelines to clarify "specific utility".

The court focused on the fact that the applicants failed identify a "specific utility" in *Brenner v. Manson*.

This requirement of one specific utility, is consistent with Unity of Invention Practice in International Applications and National Phase Applications under 35 U.S.C. 371, and PCT Rule 13.2 for PCT applications.

Therefore, applicants should rewrite claims 17 and 18 to a "specific utility".

Claim 18 violates 35 U.S.C. 101 and 35 U.S.C. 112, since it is drafted in terms of use. See *Clinical Products vs. Brenner*, 255. Supp. 151; 149 USPQ 475 (D.C. District Columbia 1966).

There is too much here to be searched. What we need here is an election of a single, heterocyclic, ring core for Z in the manner of *In re Harnish*, 206 USPQ 300 at 305 and 306.

This application contains claims directed to patentably distinct species.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits.

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a generic claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Claim 1 is generic to plurality of patentably distinct species. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even if this requirement is traversed. See 37 CFR 1.143.

Once applicants elect a species, with a specific heterocyclic ring core for Z, we have a starting point to construct a mutually arrived at generic that can be searched in the limited time made available to do so.

Note Rule 146

**1.146 Election of species.**

In the first action on an application containing a generic claim and claims restricted separately to each of more than one species embraced thereby, the examiner may require the applicant in his response to that action to elect that species of his or here invention to which his or here claim shall be restricted if no generic claim is held allowable. However, if such application contains claims directed to more than a reasonable number of species, the examiner may require restriction of the claims to not more than a reasonable number of species before taking further action in the case.

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Note Rule 105

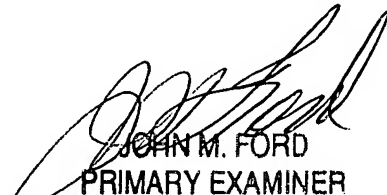
**1.105 Completeness of examiner's action.**

The examiner's action will be complete as to all matters, except that in appropriate circumstances, such as misjoinder of invention, fundamental defects in the application, and the like, the action of the examiner may be limited to such matters before further action is made. However, matters of form need not be raised by the examiner until a claim is found allowable.

We have to know what is being claimed before further action can be taken.

J. M. Ford:jmr

October 7, 2003

  
JOHN M. FORD  
PRIMARY EXAMINER  
GROUP - ART UNIT 1624